DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

M2693N

CERTIFIED MAIL
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MQSA FACILITY ID# 204099
CFN# 1060653

WARNING LETTER

FLA-99-65

May 26, 1999

Octavio A. Prieto, M.D.
Jordan & Prieto, P.A.
4302 W. Broward Boulevard
Plantation, Florida 33317

Dear Dr. Prieto:

Investigator D. Janneth Caycedo of the Food and Drug Administration (FDA), Florida District visited your facility on March 19-23 and April 2-6, 1999. The purpose of her visit was to investigate a complaint referred to the FDA alleging that Jordan & Prieto, P.A. (Jordan & Prieto) was conducting mammography without a valid FDA Mammography Facility Certificate (FDA certificate). The Mammography Quality Standards Act of 1992 (MQSA) provides that no facility may conduct examinations or procedures involving mammography after October 1, 1994, unless the facility obtains an FDA certificate (42 U.S.C. 263b(b)(1)(A)). During the March 23, 1999 visit you told Investigator Caycedo that your facility had already ceased performing mammography examinations or procedures and would not resume performing mammography until Jordan & Prieto applied for and was issued a valid FDA certificate.

Jordan & Prieto had been provisionally accredited by the American College of Radiology and provisionally certified by FDA between December 20, 1994 and June 20, 1995. Jordan & Prieto was issued a 90-day extension of its provisional certificate that expired on September 18, 1995. Jordan & Prieto's application for accreditation was denied in October of 1995. In correspondence dated October 18, 1995, FDA advised Jordan & Prieto that its accreditation body had

notified FDA of the denial of accreditation and that Jordan & Prieto was no longer certified by FDA to perform mammography. Our recent investigation revealed that Jordan & Prieto conducted mammography examinations or procedures after the September 18, 1995 expiration of its FDA certificate. Jordan & Prieto voluntarily ceased performing mammography on or about March 19, 1999.

Our investigation also revealed that your facility failed to comply with the minimum standards for documentation required for legal operation of a mammography facility. Failure to comply with the minimum quality standards for mammography were identified and include, but are not limited to, the following:

Personnel Requirements - Interpreting Physician (21 CFR 900.12(a)(1)

There was no documentation available to substantiate that the interpreting physicians, [redacted], and [redacted] had:

(a) met either the requirement of being board certified by any of the approved boards (21 CFR 900.12(a)(1)(ii)(A)); or

two months full-time training in the interpretation of mammograms (21 CFR 900.12(a)(1)(ii)(B)); and

met the initial training requirement of having received 40 hours of continuing medical education in mammography (21 CFR 900.12(a)(1)(ii)(C); and

(b) met the initial experience requirement of having read or interpreted mammograms from the examinations of a minimum of 240 patients in the six months preceding the application (21 CFR 900.12(a)(1)(iii)(A)); or

read and interpreted mammograms of a least 240 patients under the direct supervision of a qualified interpreting physician (21 CFR 900.12(a)(1)(iii)(B)).

(c) met the continuing experience requirement of having read and interpreted mammograms from an average of 960 patient examinations over the previous 36 month period (an average of five credits/year) (21 CFR 900.12(a)(iv)(A)); and

met the continuing experience requirement of having completed a minimum of 15 credits in the previous 36 month period (an average of five credits/year)(21 CFR 900.12 (a)(1)(iv)(B)).

Personnel Requirements - Radiologic Technologist [21 CFR 900.12(a)(2)]

There was no documentation available to substantiate that Radiologic Technologists [redacted], [redacted] or any other radiologic technologist ever employed by the facility that performed mammography after October 1, 1994:

(a) had met the requirement of being licensed by a State (21 CFR 900.12(a)(2)(i)) or board certified by any of the bodies approved by FDA to certify radiologic technologists (21 CFR 900.12(a)(2)(ii)); and

(b) for those radiologic techologists associated with facilities that applied for accreditation before October 1, 1996, had met the requirement of having received specific training in mammography, either through a training curriculum or special mammography course, and had accumulated at least an average of five continuing education units per year related to mammography (21 CFR 900.12(a)(2)(iii)(A)); and

(c) had one year of experience in mammography and by October 1, 1996, had met the requirement of having received specific training in mammography course, and had accumulated at least an average of five continuing education units per year related to mammography (21 CFR 900.12(a)(2)(iii)(B)).

Quality Assurance - Equipment (21 CFR 900.12(d)(1))

There was no documentation available to substantiate that:

a) processor Quality Control (QC) tests were performed since September 18, 1995 (21 CFR 900.12(d)(1)(i));

b) QC tests were performed and charted for the following:

Darkroom Fog, Screen Film contact, Fixer Retention Analysis, and Compression (21 CFR 900.12(d)(1)(i)); and

c) Quality Assurance (QA) program was in place. Missing items included the following:

Personnel Responsibilities, QC Test Procedures, Equipment Use and Maintenance Procedures, Technique Tables/Charts, and Service Records (21 CFR 900.12(d)(1)(i)).

Quality Assurance - Phantom Images (21 CFR 900.12(d)(2))

There were no phantom image QC charts present.

There was no documentation available to substantiate that phantom image QC tests were either performed or charted after the September 18, 1995 expiration of the facility's certificate.

The phantom image quality evaluation performed by Investigator Caycedo on April 6, 1999, using an FDA-approved mammography phantom, received failing scores for fibers, specks and masses.

Quality Assurance - Clinical (21 CFR 900.12(d)(3))

There was no documentation available to substantiate that repeat analysis was performed.

Quality Assurance - Clinical Image Interpretation (21 CFR 900.12(d)(4))

There was no documentation available to substantiate that a medical audit system to track positive mammograms was in place.

Quality Assurance - Surveys (21 CFR 900.12(d)(5)).

There was no documentation available to substantiate that after the September 18, 1995 expiration of the facility's certificate:

a) a physicist survey for the x-ray unit had been performed since September 18, 1995; and

b) corrective actions were taken when called for in the medical physicist's survey report.

Finally, an application was not submitted to an accreditation body and a valid certificate was not obtained since the facility was denied accreditation in October, 1995 (21 CFR 900.11).

As a result of our investigational findings, FDA has serious concerns about the quality of mammography performed by Jordan & Prieto. Therefore, FDA is requesting that Jordan & Prieto contact ACR and arrange to have an Additional Mammography Review (AMR) conducted to assess the quality of all mammography performed by Jordan & Prieto pursuant to 21 CFR 900.12(j)(1).

Jordan & Prieto will be responsible for the payment of all fees charged by ACR for conducting the AMR. The review will assess whether there has been a compromise of quality sufficient to pose a serious risk to human health. If the results of the AMR indicate that the quality of mammography produced by your facility poses a serious risk to human health, FDA may require that your facility submit a plan for a patient notification program under 42 U.S.C. 263b(h)(2) and 21 CFR 900.12(j)(2).

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- your future plans for conducting mammography;
- whether you intend to request an AMR by the ACR and, if the results of the AMR reveal that there has been a compromise of quality sufficient to pose a serious risk to human health, if you intend to conduct a patient notification program;
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment setting (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please send your written response to:

Timothy J. Couzins
555 Winderley Place
Suite 200
Maitland, Florida 32751

Additionally, FDA regulations do not preclude States and local jurisdictions from independently enforcing their own laws and regulations. In some cases, those requirements may be more stringent than FDA's. Therefore, when you plan your corrective actions, you should consider the more stringent State or local jurisdictional requirements, if any.

FDA's investigational findings demonstrate that your facility has engaged in serious violations of the MQSA, including performing mammography examinations or procedures without a valid FDA certificate and otherwise failing to comply with the MQSA. FDA may, without further notice, initiate further regulatory action(s) such as:

Assessing civil money penalties in an amount not to exceed $10,000 against an owner, operator, or any employee of a facility required to have a certificate, for:

- failure to obtain a certificate (42 U.S.C. 263b(b)(h)(3)(A)),
- each failure to substantially comply with the quality standards (21 U.S.C. 263b(b)(h)(3)(B)),
- each failure to notify a patient of risk (42 U.S.C. 263b(h)(3)), and
- each violation, or for aiding or abetting in a violation of any provision of the MQSA or FDA's implementing mammography regulations (21 CFR Part 900 (42 U.S.C. 263b(h)(3)(D)).

Seeking an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health. (43 U.S.C. 263b(j)).

If you have any questions regarding this letter or your response, please contact Tim Couzins at (407) 475-4728.

Sincerely,

Douglas D. Tolen
Director, Florida District

cc: Mr. Charles Showalter
Director, Federal Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091

Mr. Dan Oakey
State Mammography Coordinator
Florida Department of Health
Bureau of Radiation Control
Jacksonville, Florida 32231